DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 20 1997

Re: EXCENEL® Sterile Suspension
Docket No. 96E-0269

#20

RECEIVED

FEB 24 1997

PATENT EXTENSION
A/C PATENTS

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4.902,683, filed by Pharmacia & Upjohn Company, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for EXCENEL® Sterile Suspension, the animal drug product claimed by the patent.

The total length of the review period for EXCENEL® Sterile Suspension is 900 days. Of this time, 881 days occurred during the testing phase and 19 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 512(j) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: November 10, 1993.

   FDA has verified the applicant's claim that November 10, 1993 was the date that the Investigational New Animal Drug application became effective.

2. The date the application was initially submitted with respect to the animal drug product under subsection 512(b) of the Federal Food, Drug, and Cosmetic Act: April 8, 1996.

   The applicant claims April 3, 1996, as the date the New Animal Drug Application (NADA) for EXCENEL® Sterile Suspension (NADA 140-890) was initially submitted. However, a review of FDA records reveals that the date of FDA's official acknowledgement that the NADA was sufficiently complete to begin review was a telephone call requesting that certain additional information be added to the NADA on April 8, 1996, which is considered to be the initially submitted date for the NADA.

3. The date the application was approved: April 26, 1996.

   FDA has verified the applicant's claim that NADA 140-890 was approved on April 26, 1996.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

for Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Martha A. Gammil
Pharmacia & Upjohn
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